

Mark Brown Consulting

✧ Software Development / Electronic Data Capture Consulting ✧

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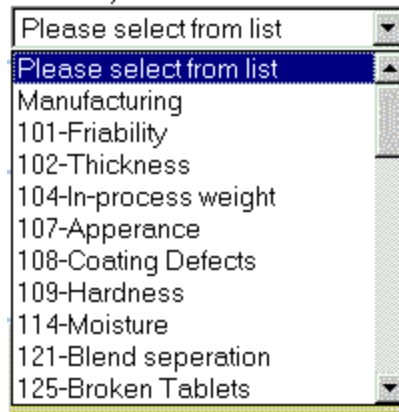
Docket Management
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

Re: 00D-1538

Dear Docket Management Branch;

I understand the comment period has expired for the docket 00D-1538, however, I would like to add a comment that should be addressed. The comment pertains to software applications used by companies to record and store data electronically and documented in a validation plan.

Allow me to frame the issue: Software applications being used by pharmaceutical companies contain electronic forms that allow users to input data into databases. The submission forms used by these employees contain "Drop-Down" boxes (see example below) to make a selection from. This tool allows users to choose information that has been pre-populated by the Software Company or System Administrator to be included in their electronic submission.



The user would review their choices and click one of the items in the list. If it were a required field, the user would be asked to select something before submitting.

The intent of this question is to clarify whether or not a IQ/OQ/PQ test must reside in the validation plan for each and every choice in the "Drop-Down" box or if an alternative approach can be used.

A concern by some pharmaceutical companies has been to include a test for every choice in the drop-down box; this approach does not address that dynamic nature of the tool. Since the content of the drop-down may change over time, it seems more appropriate to test each occurrence of a drop down as follows;

- A.) Document the criteria for the contents of the list and incorporate the managerial approval(s) into the validation plan.
- B.) Perform a "Challenge Test" on the form to insure the user must choose something from the list if it is a required field.
- C.) If it is not a required field, note the default value it will send to the database.
- D.) If the user can choose multiple items at one time from the drop-down box, clarify and test.
- E. If the drop-down can be substituted with an alternative value input by the user, document and test.
- F. Document the Standard Operating Procedures and authority levels required to change the information in the drop-down box(s) through a "Change Control" SOP.

By providing objective evidence within the validation plan and addressing these issues, the need for tests on every choice within a drop-down box can be eliminated.

Your feedback regarding this issue will be helpful for current and existing validation work.

Respectfully,

Mark R. Brown
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